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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,949	01/23/2004	Andrei Darievich Mirzabekov	U 014998.5	5066
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EXAMINER				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/763,949

Applicant(s)

MIRZABEKOV ET AL.

Examiner

Amber D. Steele

Art Unit

1639

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-77 is/are pending in the application.
- 4a) Of the above claim(s) 66-67 and 69-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-65, 68 and 72-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date 7/19/04: 4/8/04
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-34 were originally filed on January 23, 2004.

The amendment to the claims received on October 3, 2006 canceled claims 1-17 and added new claims 35-51.

The amendment to the claims received on May 23, 2007 canceled claims 18-51 and added new claims 52-77.

The amendment to the claims received on October 1, 2007 changed the status identifiers only.

The amendment to the claims received on November 27, 2007 amended claims 52, 54, and 59.

Claims 52-77 are currently pending.

Claims 52-65, 68, and 72-75 are currently under consideration.

Election/Restrictions

2. Regarding the initial restriction requirement mailed on June 30 2006, applicants elected Group XIX (claims 52-75) in the reply filed on October 1, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 76-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made without traverse in the reply filed on October 1, 2007.

4. Regarding the secondary restriction mailed on December 3, 2007, Applicant's election of Group I (claims 65 and 68; linking claims 52-64 and 72-75) in the reply filed on March 24, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

5. Claims 66-67 and 69-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 24, 2008.

6. Applicant's election of H as the species of R^1 and R^2 , CH_3 as the species of R^3 , $(CH_2)_2OH$ as the species of R^4 , $p-C_6H_4$ as the species of Y, $(CH_2)_2OX$ as the species of Z, and POO_3H as the species of X in the reply filed on March 24, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

7. The presently claimed invention claims status as a CON of PCT/RU01/00445 filed October 26, 2001 and claims foreign priority to RU 2001120905 filed July 25, 2001.

8. Please note: A certified copy of the international application (and an English translation) of the international application may be required by the examiner to perfect the claim for benefit

under 35 U.S.C. 120 and 365(c) if the international application did not originate in the United States and such is necessary, for example, where an intervening reference is found and applied in a rejection of one or more claims. See MPEP § 1895.01.

9. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

10. Since a certified copy and an English language translation of PCT/RU01/00445 was not provided, intervening art is being utilized in the rejections (i.e. the present priority date perfected is January 23, 2004 which is the filing date of the present application).

Information Disclosure Statement

11. The information disclosure statements (IDS) submitted on July 19, 2004 and April 8, 2004 are being considered by the examiner.

Claim Objections

12. Claim 52 is objected to because of the following informalities: The phrase "a, b, c, d, e" should read "a, b, c, d, and e". In addition, section (b) is present without a corresponding section (a). Insertion of section (a) or cancellation of "(b)" is suggested. Appropriate correction is required.

13. Claim 61 is objected to because of the following informalities: a space between the comma and N-[tris(hydroxymethyl)methyl]acrylamide is required. Appropriate correction is required.

14. Claim 63 is objected to because of the following informalities: claim 63 reads “wherein the cross-linking agent B is one of more...and...”. “[W]herein the cross-linking agent B is one or more of...or...” or “wherein the cross-linking agent B is...or...” is suggested. Appropriate correction is required.

15. Claim 63 is objected to because of the following informalities: N,N'-methylenebisacrylamide and N,N'-ethylenebismethacrylamide are considered typographical errors. N,N'-methylenebisacrylamide and N,N'-ethylenebismethacrylamide are suggested. Appropriate correction is required.

16. Claims 65 and 68 are objected to because of the following informalities: The r and t variables should be n (see original claims 6, 9, and 18 filed January 23, 2004). Appropriate correction is required.

Invention as Claimed

17. Linking Claim: A biochip comprising an array of gel cells formed on a substrate by copolymerization of composition K wherein $K = aA + bB + cC + dD + eE$ wherein A is a monomer based on derivatives of acrylic and methacrylic acids; B is a water soluble cross-linking agent; C is a biological modified macromolecule bearing an unsaturated group; D is a water soluble compound as a medium component for performing a copolymerization; E is water, and a, b, c, d, and e are percentages (X) of each ingredient in the composition wherein for solids X is $m/v \times 100\%$ and for liquids X is $v/v \times 100\%$ wherein the total content of monomer and cross-

linking agent is in a range from 3 to 40% ($3 \leq (a+b) \leq 40\%$) and a monomer to cross-linking agent ration being within a range of 97:3 to 60:40 and percentages of C, D, and E ingredients being within a range of $0.0001\% \leq c \leq 10\%$; $0\% \leq d \leq 90\%$; $5\% \leq e \leq 95\%$; and wherein each cell may include an immobilized macromolecule and variations thereof.

18. The phrases “by copolymerization” and “performing a copolymerization” (claim 52) are considered product-by-process limitations. Claims 54-60 are considered product-by-process claims. See MPEP § 2113.

The intended use limitations of “used separately or as a mixture” (claims 62 and 64) are not provided patentable weight. See MPEP § 2106, section II.

The product-by-process/intended use limitations of claims 74-75 are not provided patentable weight. See MPEP § 2113 and § 2106, section II.

The limitations regarding the specific ratio/ranges of the various ingredients are considered normal optimization conditions in the art (see MPEP § 2144.05, section II).

The limitation of “may include an immobilized macromolecule” (claim 52) is considered an optional limitation.

Claim Rejections - 35 USC § 102/35 USC § 103

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 52-62, 64-65, 68, and 74-75 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vasiliskov et al., Fabrication of Microarray of Gel-Immobilized Compounds on a Chip by Copolymerization, *Biotechniques*, 27: 592-606, 1999 (provided by applicants in the IDS).

For present claims 52-62, 64-65, 68, and 74-75, Vasiliskov et al. teach microarrays of gel cells with immobilized modified DNA (C) wherein acrylamide (A), bisacrylamide (B), TEMED (D), water, and glycerol are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3).

Therefore, the presently claimed invention is anticipated by the teachings of Vasiliskov et al.

21. Claims 52-62, 64-65, 68, and 74-75 are rejected under 35 U.S.C. 103(a) as obvious over Rehman et al., Immobilization of acrylamide-modified oligonucleotides by co-polymerization, *Nucleic Acids Research*, 27(2): 649-655, 1999 (provided by applicants in the IDS).

For present claims 52-62, 64-65, 68, and 74-75, Rehman et al. teach microarrays of gel cells with immobilized acrylamide-modified DNA (C) wherein acrylamide (A), bisacrylamide (B), APS and TEMED (D), water, and glycerol are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3; Figure 1).

Therefore, the presently claimed invention is anticipated by the teachings of Rehman et al.

22. Claims 52-65, 68, and 72-75 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abrams et al. U.S. application publication 2003/0143569 published July 31, 2003.

For present claims 52-65, 68, and 72-75, Abrams et al. teach gel arrays comprising immobilized acrylamide-modified DNA (C), acrylamide and 2-hydroxyethylmethacrylate (A), methylenebisacrylamide (B), DMF or DMSO (D), water, and glycerol (please refer to the entire reference particularly the abstract; Figures 1 and 8-9; paragraphs 3, 13-51, 56-68, 79, 92-123, 129-131; Examples 1-18).

Therefore, the presently claimed invention is anticipated by the teachings of Abrams et al.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claims 52-65, 68, and 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vasiliskov et al., Fabrication of Microarray of Gel-Immobilized Compounds on a Chip by Copolymerization, Biotechniques, 27: 592-606, 1999 (provided by applicants in the IDS) and Solomon et al. U.S. Patent 6,585,873.

For present claims 52-62, 64-65, 68, and 74-75, Vasiliskov et al. teach microarrays of gel cells with immobilized modified DNA (C) wherein acrylamide (A), bisacrylamide (B), TEMED

(D), water, and glycerol are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3).

However, Vasiliskov et al. does not teach the species of (B) recited in claim 63.

For present claim 63, Solomon et al. teach hydrophilic gels comprising copolymerized acrylamide, N,N'-methylenebisacrylamide, DMF, glycerol, and water (please refer to the entire specification particularly the abstract; Figure 1; columns 1-2, 6-7, 9; Examples 1-20).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the hydrogel taught by Vasiliskov et al. with specific species of bisacrylamide taught by Solomon et al.

One having ordinary skill in the art would have been motivated to do this because Solomon et al. teaches that N,N'-methylenebisacrylamide and acrylamide copolymerization is conventional in the art (please refer to column 1, lines 25-28).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the hydrogel taught by Vasiliskov et al. with specific species of bisacrylamide taught by Solomon et al. because of the examples taught by Solomon et al. (see Example 5).

Therefore, the modification of the hydrogel taught by Vasiliskov et al. with specific species of bisacrylamide taught by Solomon et al. render the instant claims *prima facie* obvious.

25. Claims 52-65, 68, and 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman et al., Immobilization of acrylamide-modified oligonucleotides by copolymerization, *Nucleic Acids Research*, 27(2): 649-655, 1999 (provided by applicants in the IDS) and Solomon et al. U.S. Patent 6,585,873.

For present claims 52-62, 64-65, 68, and 74-75, Rehman et al. teach microarrays of gel cells with immobilized acrylamide-modified DNA (C) wherein acrylamide (A), bisacrylamide (B), APS and TEMED (D), water, and glycerol are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3).

However, Rehman et al. do not teach the species of (B) recited in claim 63.

For present claim 63, et al. Solomon teach hydrogels comprising acrylamide, N,N'-methylenebisacrylamide, DMF, glycerol, and water (please refer to the entire specification particularly the abstract; Figure 1; columns 1-2, 6-7, 9; Examples 1-20).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the hydrogel taught by Rehman et al. with specific species of bisacrylamide taught by Solomon et al.

One having ordinary skill in the art would have been motivated to do this because Solomon et al. teaches that N,N'-methylenebisacrylamide and acrylamide copolymerization is conventional in the art (please refer to column 1, lines 25-28).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the hydrogel taught by Rehman et al. with specific species of bisacrylamide taught by Solomon et al. because of the examples taught by Solomon et al. (see Example 5).

Therefore, the modification of the hydrogel taught by Rehman et al. with specific species of bisacrylamide taught by Solomon et al. render the instant claims *prima facie* obvious.

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 52-65, 68, and 72-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-54 of copending Application No. 10/450,641. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. application 10/450,641 are drawn to biochips.

For present claims 52-65, 68, and 72-75, U.S. application 10/450,641 claims biochips with cells comprising immobilized molecules made by the method of polymerizing a composition comprising $K = aA + bB + cC + eE + fF$ wherein A is acrylamide, etc.; B is N,N'-methylenebisacrylamide, etc.; C is oligonucleotide, nucleic acid, etc.; D is a medium for performing polymerizing immobilization; and E is water, etc. and wherein a, b, c, d, and e are percentages (X) of each ingredient in the composition wherein for solids $X = m/v \times 100\%$ and for liquids $X = v/v \times 100\%$ wherein the total content of monomer and cross-linking agent is in a range from 3 to 40% ($3 \leq (a+b) \leq 40\%$) and a monomer to cross-linking agent ration being

within a range of 97:3 to 60:40 and percentages of C, D, and E ingredients being within a range of $0.0001\% \leq c \leq 10\%$; $0\% \leq d \leq 90\%$; $5\% \leq e \leq 95\%$ (please refer to claims 25-54).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

June 5, 2008